indicated by bracketing for deleting and underlining for additions, is attached hereto as Exhibit A.

Claims 1, 3, 4 and 7 have been amended. Claims 2, 5-6, and 8-10 are canceled without prejudice. Upon entry of the present amendments, Claims 1, 3, 4 and 7 will be pending and under active consideration. A marked version of the claims indicating the changes to the claims is attached hereto as Exhibit B, and a copy of the claims that will be pending upon entry of the present amendment is attached hereto as Exhibit C. The amendments are fully supported by the present specification and do not represent new subject matter.

Claims 1, 3, 4 and 7 have been amended to recite SEQ ID NOs:1-7, residues 67-91 of SEQ ID NO: 4, and nucleotide residues 7-30 of SEQ ID NO: 2 derived from the Primary Sclerosing Cholangitis, PSC, associated retrovirus. The amendment does not constitute new matter because support for the amendment is found at page 10, lines 35-37 wherein sequences derived from the Primary Sclerosing Cholangitis, PSC, associated retrovirus are disclosed. On page 37, lines 1-31 of the specification as filed nucleotide residues 67-91 of SEQ ID NO: 4, and nucleotide residues 7-30 of SEQ ID NO: 2 are disclosed as primers and probes designed from the sequences of the novel clones identified in PSC patient bile cDNA.

Objection to the Specification

The specification is objected to because of certain informalities. In response, the specification is amended to correct typographical errors. The amendments to the specification do not constitute new matter as defined in 35 U.S.C. § 132. In view of the amendments, this objection is avoided and should be withdrawn.

Objection to the Claims

Claim 2 is objected to as being dependent on a rejected claim. In view of the cancellation of Claim 2, the Examiner's objection to Claim 2 is obviated and the objection should be withdrawn.

Rejection Based on 35 U.S.C. § 112, First Paragraph

Claims 1, 3, 4 and 7 have been rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention.

The basis for the Examiner's objection seems to be founded in the indefinite nature of the phrase "related to" and lack of support for the phrase in the specification and claims. Claim 1 is amended to eliminate the phrase "related to." Thus, a portion of the grounds for rejection are overcome.

Additionally, the Examiner rejects Claims 1, 3, 4 and 7 on the grounds that the claim does not recite the unique PSC associated retroviral sequences discovered by the applicants. Claims 1, 3, 4 and 7 are amended to recite SEQ ID NOs: 1-7, nucleotide residues 67-91 of SEQ ID NO: 4, nucleotide residues 7-30 of SEQ ID NO: 2, or a compliment thereof. Thus, the amended claims exclusively recite the unique PSC associated retroviral sequences discovered by the applicants. Applicants submit the rejection under 35 U.S.C. § 112, first paragraph has been obviated and should be withdrawn.

Rejection Based on 35 U.S.C. § 112, Second Paragraph

Claims 3, 4 and 7 remained rejected for failing to distinctly claim the subject matter which the Applicants regard as the invention. The Office Action asserts that the claims contain certain terms that lacked antecedent basis such as "the step," "the presence," and "the virus," and "the PSC pol sequence." Claims 3, 4 and 7 are amended to recite the descriptive terminology of the specification. The amended claims now contain consistent and uniform terminology. The rejections under 35 U.S.C. § 112, second paragraph are therefore overcome.

The Claimed Invention Is Not Anticipated Under 35 U.S.C. § 102 (e)

Claims 3-4 remain rejected under 35 U.S.C. 102 (e) as being anticipated by Peterson et al. as evidenced by Mason et al. The Examiner contends the claimed invention reads on any Retrovirus associated with PSC, autoimmune hepatitis, Crohn's disease or ulcerative colitis and that the HIV-1 sequence would be encompassed since, Mason

demonstrated a correlation between HIV and autoimmune diseases. Claims 3 and 4 are amended to recite the novel PSC associated retroviral sequences of the invention. In light of the amendments, the rejection under 35 U.S.C. 102 (e) is overcome.

The Claimed Invention Is Not Made Obvious Under 35 U.S.C. § 103 (a)

Claim 1-4 and 7are rejected under 35 U.S.C. § 103 (a) as being unpatentable over Mason et al. in view of Peterson et al. The Examiner's rejection is based on the assertion that the claims "broadly read on any PSC related retroviral sequences," and therefore the HIV-1 retroviral sequence disclosed by Mason would inherently qualify as a PSC associated retrovirus.

In the present instance, the relevant inquiry is whether it would be obvious to one of skill in the art that the novel PSC associated retroviral sequences discovered by the Applicants could be employed to diagnose or prognose certain autoimmune disorders. Claims 1, 4 and 7 are amended to recite the PSC retroviral sequences according to SEQ. ID. NO: 1-7, nucleotide residues 67-91 of SEQ ID NO: 4, nucleotide residues 7-30 of SEQ ID NO: 2, or a compliment thereof. The claimed invention related to novel PSC associated retroviral sequences such as SEQ ID No: 1-7, nucleotide residues 67-91 of SEQ ID NO: 4, nucleotide residues 7-30 of SEQ ID NO: 2, or a compliment thereof, and does not encompass the HIV-1 coding sequence described in Mason. Therefore, at the time of the present invention, one of skill in the art would not have had suggestion or expectation of success in relation to use of the novel sequences discovered by the Applicants. A finding of obviousness cannot be found and the rejection is in part overcome.

The prior art does not provide both a suggestion and reasonable expectation of success *In re Vaeck*, 947 F. 2d 488 (Fed. Cir. 1991). It is clear that the amendments to recite the novel sequences of the invention render the claims non-obvious over Mason et al. in view of Peterson et al. and that the Applicant's data is conclusive and distinct over Mason et al. The forgoing rejection under 35 U.S.C. § 103 (a) is in error and should be withdrawn for the reasons described above.

CONCLUSION

The applicant respectfully requests entry of the amendments and remarks made herein into the file history of the present application.

Respectfully submitted,

Date October 25, 2002

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EXHIBIT A

MARKED VERSION OF PARAGRAPH IN THE SPECIFICATION

U.S. PATENT APPLICATION SERIAL NO. 09/536,552

On page 8, please amend the paragraph beginning "Figure 1 Phylogenetic tree of Clustal," as follows:

Figure 1 Phylogenetic [Pylogenetic] tree of Clustal W alignments using reverse transcriptase pol gene sequences: PBCRV PBC retroviral sequence cloned in our laboratory, SMRV Squirrel monkey retrovirus, MPMV Mason-Pfizer monkey virus, HERVK Human Endogenous retrovirus-K, MIAP Murine intracisternal A-type particle, HRV-5 Human retrovirus 5, PSCRV PSC retroviral sequence cloned in our laboratory, HFV Human foamy retrovirus, HIV Human immunodeficiency virus, MSRV Multiple sclerosis retrovirus, MMLV Murine Moloney leukemia virus , HTLV1 Human T-cell leukemia virus-1, HBV hepatitis B virus.

On page 10, please amend the paragraph beginning "The retroviral nucleotides," as follows:

The retroviral nucleotides of the present invention are described herein. Unless otherwise stated, the term 'retroviral or viral nucleotides or nucleic acid molecules' refers collectively to the sequences described herein. The novel retroviral nucleotides of the present invention include, but are not limited to, (a) novel clones identified in samples from PSC patients [patents]:

On page 39, please amend the title of Table 5 beginning "Table 5. The Detection Rate of," as follows:

Table 5. The Detection Rate of Potential PSC Related Viral cDNA Fragment in Patients with Liver Diseases by RT-PCR [PCT] and Hybridization

EXHIBIT B

MARKED VERSION OF THE CLAIMS

U.S. PATENT APPLICATION SERIAL NO. 09/536,552

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1. (twice amended) A method for identifying an individual having a disorder comprising a step of detecting a presence or absence of a Primary Sclerosing Cholangitis, hereinafter, PSC, associated retroviral nucleic acid molecule, wherein said nucleic acid molecule comprises SEQ ID NOs: 1, 2, 3, 4, 5, 6 or 7, nucleotide residues 67-91 of SEQ ID NO: 4, nucleotide residues 7-30 of SEQ ID NO: 2, or a compliment thereof, wherein the presence of the retroviral nucleic acid molecule indicates that the individual has a disorder [related to] selected from the group consisting of PSC, Autoimmune Hepatitis, hereinafter AIH, Crohn's disease, [or] and ulcerative colitis.

3. (amended) A composition comprising an isolated Primary Sclerosing Cholangitis, PSC, associated retrovirus comprising a nucleotide sequence comprising SEQ. ID. NOs. 1, 2, 3, 4, 5, 6, 7, nucleotide residues 67-91 of SEQ ID NO: 4, nucleotide residues 7-30 of SEQ ID NO: 2, or a compliment thereof.

4. (twice amended) A method for identifying an individual infected with the [PSC] Primary Sclerosing Cholangitis, hereafter PSC, associated retrovirus comprising [a step of detecting] detection of [the presence or absence of] a PSC associate retroviral nucleic acid molecule wherein said nucleic acid molecule comprises SEQ. ID. NOs. 1, 2, 3, 4, 5, 6, 7, nucleotide residues 67-91 of SEQ ID NO: 4, nucleotide residues 7-30 of SEQ ID NO: 2, or a compliment thereof, wherein the presence of the nucleic acid molecule indicates that the individual is infected with the [virus] PSC associated retrovirus.

7. (amended) A method for identifying an *in vitro* sample infected with the [PSC] Primary Sclerosing Cholangitis, hereafter PSC, associated retrovirus comprising the step of detecting the presence or absence of the PSC associated Retroviral nucleic acid molecule wherein said nucleic acid molecule comprises SEQ. ID. NOs. 1, 2, 3, 4, 5, 6, 7, nucleotide residues 67-91 of SEQ ID NO: 4, nucleotide residues 7-30 of SEQ ID NO:

2, or a compliment thereof, wherein the presence of the nucleic acid molecule indicates that the sample is infected with the [virus] PSC associated retrovirus.